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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,406

09/12/2003

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/661,406	Applicant(s) WU ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4,6-9,13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4,6-9,13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/08/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

35 USC § 112 Sixth Paragraph

1. It is assumed that applicant has intended to invoke 112 sixth paragraph as per the means for language set forth in the claims.
 - a. In Claim 4, “means for evacuating air” is interpreted by the specification to be openings in the inner catheter or equivalents thereof.
 - b. In Claim 11, “means for preventing unintentional movement of the gear rack” is interpreted by the specification to be a locking arm or equivalents thereof
 - c. In claim 12 and 14, “means for allowing motion of the gear rack in only one direction” is interpreted by the specification to be a spring or equivalents thereof.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 13, 15 and 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan III, et al (US 5,968,052) in view of Failla et al. (USPN 5,501,654).**

4. Sullivan discloses a system for delivering and deploying a medical device within a patient (see entire document, specifically Figures 10-15), the system comprising a delivery catheter including an inner catheter member (12) having a region for mounting the medical device (18) thereon and an outer restraining member (14) co-axially disposed over the inner catheter member and the medical device. The outer restraining member is adapted for axial movement with respect to the inner catheter member (Fig. 3, 13 and 14). A control handle (Fig. 12 and 15) connected to a retraction mechanism and the inner catheter member has a proximal end attached to the control handle (52, fig. 9-11) and the outer restraining member having a proximal end attached to the retraction mechanism. A trigger mechanism (46) causes linear movement of the retraction mechanism to proximally retract the outer restraining member sheath to uncover the medical device while the inner catheter member remains stationary (C5: L16-21). The retraction mechanism includes a gear rack (84) which is slidable in a channel (90) of the handle and a spur gear (70) which engages (indirectly) the gears of the gear rack, and an actuating gear (68) that engages the spur gear and causes the gear rack to move (C4:L52-C6:L4) linearly. The stop means (48) prevents unintentional movement of the gear rack (C4:L10-15). The means for allowing motion of the gear rack in only one direction is a spring (92) that contacts the distal surface of the gears on the gear rack to prevent distal movement (C5:L5-13) .

5. Sullivan does not disclose that the actuating gear is a thumbwheel, but rather that it is a trigger. However Failla discloses a surgical device using a thumbwheel for actuating a gear to axially move a rack to retract a distal portion of the device.

6. The substitution of one known element (thumbwheel) for another (trigger mechanism) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the thumbwheel shown in Failla would have yielded predictable results, namely, a smooth continuous retraction of the sheath during stent deployment. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

7. Regarding claim 15, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an anti-clotting agent into a stent delivery device since it is well known in the art to deliver drugs at the time of stent delivery to prevent further trauma to the tissue that is being treated. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

8. Claims 2, 6, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Failla (US 5,501,654) as applied to claim 13 above and further in view of Fitz (USPN 6,146,415).

9. Sullivan in view of Failla discloses the invention substantially as claimed as stated above except for an outer sheath, which is attached to the control handle to prevent the inner catheter member from moving distally when the outer restraining member is retracted. Sullivan in view of Failla does not disclose that the guide wire lumen extends from the proximal end to the distal end of the catheter

10. Fitz discloses a stent delivery system that comprises an inner catheter (10), a restraining sheath (16) analogous to that which is disclosed by Gilson. Fitz further discloses the use of a guide catheter with a coupling member (40) wherein the proximal the position of the catheter handle with respect to the guide catheter (Col 6, line 56-62). The outer sheath is removably attached to the control handle (50). Fitz states that this feature is an improvement to stent delivery catheters because it prevents unwanted movement of the device during delivery and provides grater accuracy of stent placement. Fitz discloses stent delivery system which can be quick exchange or over the wire thereby having a guidewire lumen that extends from the distal end to the proximal end.

11. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a guide catheter since it is well known in the art to use a guide catheter to provide a stable channel for delivering working catheters to the body. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a guide catheter with a coupling member into the stent delivery device to enhance the function of the device by ensuring accurate delivery of the stent. Fitz provides the motivation which is well within the scope of the invention. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify a stent delivery device to be quick exchange or over the wire depending on the needs of the user and the method of use. It is well known in the art to interchange over the wire catheters with quick exchange catheters. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

12. Regarding claim 16, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate an anti-clotting agent into a stent delivery device since it is well known in the art to deliver drugs at the time of stent delivery to prevent further trauma to the tissue that is being treated. Since applicant failed to traverse examiner's assertion, the common knowledge or well-known in the art statement is taken to be admitted prior art (MPEP 2144.03 C).

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Failla et al. (USPN 5,501,654) as applied to claim 13 above and further in view of Stack et al (6,860,898).

14. Sullivan in view of Failla discloses the invention substantially as claimed as stated above except for the means for evacuating air. Stack discloses a stent delivery device. The device provides openings (49) in the catheter for allowing the evacuation of air.

15. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate flushing system including holes for evacuating air since it is well known in the art as evidenced by Stack. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

16. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Failla (US 5,501,654) in view of Fitz (USPN 6,146,415) as applied to claim 19 above, and further in view of Kratoska et al. (USPN 6,183,443)

17. Sullivan modified by Failla and Fitz discloses the instant invention substantially as claimed as stated above except for “the outer sheath is attached to a strain relief member, which is removably attached”. Kratoska discloses an introducer sheath having a proximal end attached to a strain relief member. The introducer of Kratoska is a separate entity from the device that is being inserted into it just as in Sullivan in view of Failla. The introducer has a distal portion that has a smaller inner diameter than a proximal portion of the sheath.

18. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a strain relief into the introducer since it is well known in the art to use a strain relief as evidenced by Kratoska to reduce buckling or kinking.

19. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan in view of Failla in view of Fitz in view of Kratoska as applied to claim 7 above, and further in view of Lowery et al (USPN 4,624,243).

20. Sullivan modified by Failla, Fitz and Kratoska discloses the instant invention substantially as claimed as stated above except for “the strain relief having a channel for receiving a tab like member of the control handle”. Lowery discloses that it is old and well known in the art to use a threaded connection between an introducer and a medical device. The spaces between the threads of the introducer are analogous with the channel of the strain relief and the projecting threads of the medical device are analogous with the taps on the control handle.

21. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate threads into the introducer and the medical device since it is old and well known in the art. Furthermore it provides the advantage of stabilizing the device while performing the medical procedure.

Response to Arguments

22. Applicant's arguments filed 04/20/07, where applicant previously addressed the combination of Sullivan and Failla, have been fully considered but they are not persuasive. Applicant states that replacing the trigger mechanism of Sullivan with the thumbwheel of Failla would not allow the Sullivan device to operate properly since it would not allow the back and forth movement needed to retract the sheath. However, with the use of the thumbwheel, there would be no need for a back and forth motion since the thumbwheel would provide a continuous flow of movement as taught by Failla. It would be well within the skill of the ordinary artisan to determine that replacing the trigger with the thumbwheel would merely require a longer gear rack as taught by Failla.

23. Applicant goes on to state that there is an incongruity between the Sullivan and the Failla patent since Failla is moving the inner rod and in Sullivan the inner rod is stationary. However this fact is irrelevant to the combination. Failla is being used for the mechanism of the thumbwheel translating rotational movement to axial movement, regardless of element is actually being moved.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731